

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number : 074107

**Trade Name : ATENOLOL AND CHLORTHALIDONE
TABLETS USP**

**Generic Name: Atenolol and Chlorthalidone Tablets USP,
50mg/25mg and 100mg/25mg**

Sponsor : Sidmak Laboratories, Inc.

Approval Date: September 24, 1997

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION 074107

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tentative Approval Letter				
Approvable Letter				
Final Printed Labeling	X			
Medical Review(s)				
Chemistry Review(s)	X			
EA/FONSI				
Pharmacology Review(s)				
Statistical Review(s)				
Microbiology Review(s)				
Clinical Pharmacology Biopharmaceutics Review(s)				
Bioequivalence Review(s)	X			
Administrative Document(s)				
Correspondence				

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **074107**

APPROVAL LETTER

SEP 24 1997

Sidmak Laboratories, Inc.
Attention: Jairaj U. Mehta
17 West Street
P.O. Box 371
East Hanover, NJ 07936

Dear Sir:

This is in reference to your abbreviated new drug application dated August 22, 1991, submitted pursuant to Section 505(j) of the Food, Drug, and Cosmetic Act for Atenolol and Chlorthalidone Tablets USP, 50 mg/25 mg and 100 mg/25 mg.

Reference is also made to your amendments dated November 4, 1992, January 4, 1993, September 25, 1996, and May 5, July 7, and August 27, 1997.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Atenolol and Chlorthalidone Tablets USP, 50 mg/25 mg and 100 mg/25 mg tablets to be bioequivalent and therefore therapeutically equivalent to those of the listed drug (Tenoretic-50 Tablets and Tenoretic-100 Tablets, respectively, of Zeneca Pharmaceuticals). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER **074107**

FINAL PRINTED LABELING

NDC 50111-509-01

**Atenolol and
Chlorthalidone
Tablets, USP**

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

100 Tablets

Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined in the USP.

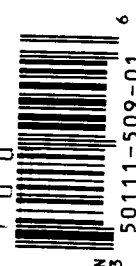
Store at controlled room temperature 15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as directed by physician. See package insert.

Control No.
Exp. Date
Iss. 5/06

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-509-01

**Atenolol and
Chlorthalidone
Tablets, USP**

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

100 Tablets

Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined in the USP.

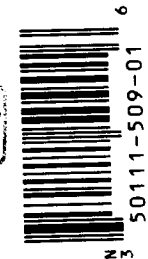
Store at controlled room temperature 15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as directed by physician. See package insert.

Control No.
Exp. Date
Iss. 5/06

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-509-01

**Atenolol and
Chlorthalidone
Tablets, USP**

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

100 Tablets

Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined in the USP.

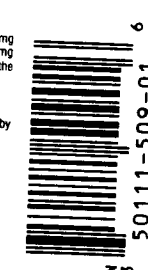
Store at controlled room temperature 15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as directed by physician. See package insert.

Control No.
Exp. Date
Iss. 5/06

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-509-01

**Atenolol and
Chlorthalidone
Tablets, USP**

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

100 Tablets

Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined in the USP.

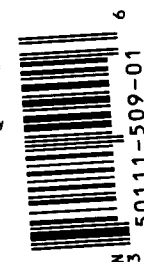
Store at controlled room temperature 15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as directed by physician. See package insert.

Control No.
Exp. Date
Iss. 5/06

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



m. 10/10/06

NDC 50111-508-03

Atenolol and Chlorthalidone Tablets, USP

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

1000 Tablets

Sidmak
LABORATORIES, INC.

EACH TABLET CONTAINS:

Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as defined
in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

Control No.:

Exp. Date:

Iss. 5/96

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-03

Atenolol and Chlorthalidone Tablets, USP

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

1000 Tablets

Sidmak
LABORATORIES, INC.

EACH TABLET CONTAINS:

Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as defined
in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

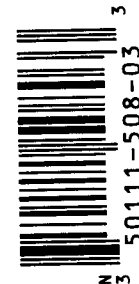
Control No.:

Exp. Date:

Iss. 5/96

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-03

Atenolol and Chlorthalidone Tablets, USP

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

1000 Tablets

Sidmak
LABORATORIES, INC.

EACH TABLET CONTAINS:

Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as defined
in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

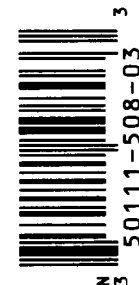
Control No.:

Exp. Date:

Iss. 5/96

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-03

Atenolol and Chlorthalidone Tablets, USP

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

1000 Tablets

Sidmak
LABORATORIES, INC.

EACH TABLET CONTAINS:

Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as defined
in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

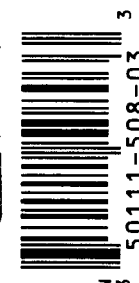
Control No.:

Exp. Date:

Iss. 5/96

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-02

Atenolol and Chlorthalidone Tablets, USP

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

500 Tablets

Sidmak
LABORATORIES, INC.

EACH TABLET CONTAINS:

Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as defined
in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

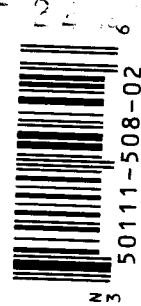
USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

Control No.:

Exp. Date:

Iss. 5/96

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-02

Atenolol and Chlorthalidone Tablets, USP

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

500 Tablets

Sidmak
LABORATORIES, INC.

EACH TABLET CONTAINS:

Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as defined
in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

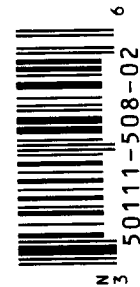
USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

Control No.:

Exp. Date:

Iss. 5/96

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-02

Atenolol and Chlorthalidone Tablets, USP

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

500 Tablets

Sidmak
LABORATORIES, INC.

EACH TABLET CONTAINS:

Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as defined
in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

Control No.:

Exp. Date:

Iss. 5/96

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-02

Atenolol and Chlorthalidone Tablets, USP

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

500 Tablets

Sidmak
LABORATORIES, INC.

EACH TABLET CONTAINS:

Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as defined
in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

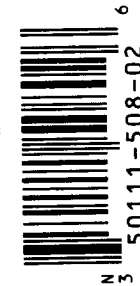
USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

Control No.:

Exp. Date:

Iss. 5/96

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



170267

NDC 50111-509-02

**Atenolol and
Chlorthalidone
Tablets, USP**

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

500 Tablets

Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined
in the USP.
Store at controlled room temperature
15°-30°C (59°-86°F).
USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

Control No.:
Exp. Date:
Iss. 5/96

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-509-02

**Atenolol and
Chlorthalidone
Tablets, USP**

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

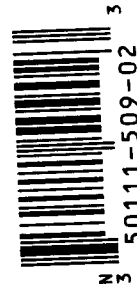
500 Tablets

Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined
in the USP.
Store at controlled room temperature
15°-30°C (59°-86°F).
USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

Control No.:
Exp. Date:
Iss. 6/96

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-509-02

**Atenolol and
Chlorthalidone
Tablets, USP**

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

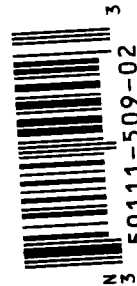
500 Tablets

Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined
in the USP.
Store at controlled room temperature
15°-30°C (59°-86°F).
USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

Control No.:
Exp. Date:
Iss. 5/96

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-509-02

**Atenolol and
Chlorthalidone
Tablets, USP**

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

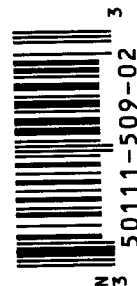
500 Tablets

Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined
in the USP.
Store at controlled room temperature
15°-30°C (59°-86°F).
USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.

Control No.:
Exp. Date:
Iss. 5/96

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-01

**Atenolol and
Chlorthalidone
Tablets, USP**

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

100 Tablets

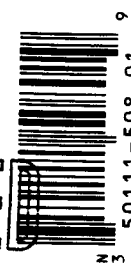
Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined in the
USP.
Store at controlled room temperature 15°-30°C
(59°-86°F).
USUAL DOSAGE: One tablet daily, or as directed by
physician. See package insert.

Control No.
Exp. Date
Iss. 5/96

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-01

**Atenolol and
Chlorthalidone
Tablets, USP**

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

100 Tablets

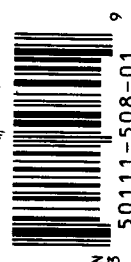
Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined in the
USP.
Store at controlled room temperature 15°-30°C
(59°-86°F).
USUAL DOSAGE: One tablet daily, or as directed by
physician. See package insert.

Control No.
Exp. Date
Iss. 5/96

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-01

**Atenolol and
Chlorthalidone
Tablets, USP**

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

100 Tablets

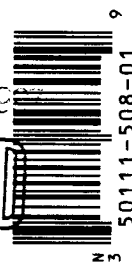
Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined in the
USP.
Store at controlled room temperature 15°-30°C
(59°-86°F).
USUAL DOSAGE: One tablet daily, or as directed by
physician. See package insert.

Control No.
Exp. Date
Iss. 5/96

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-508-01

**Atenolol and
Chlorthalidone
Tablets, USP**

50 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

100 Tablets

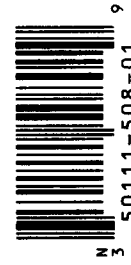
Sidmak.
LABORATORIES, INC.

EACH TABLET CONTAINS:
Atenolol, USP 50 mg
Chlorthalidone, USP 25 mg
Dispense in a well-closed container as defined in the
USP.
Store at controlled room temperature 15°-30°C
(59°-86°F).
USUAL DOSAGE: One tablet daily, or as directed by
physician. See package insert.

Control No.
Exp. Date
Iss. 5/96

APPROVED

SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936



NDC 50111-509-03

Atenolol and Chlorthalidone Tablets, USP

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

1000 Tablets



EACH TABLET CONTAINS:

Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as
defined in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.



SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936

Control No.:
Exp. Date:
Iss. 5/96

NDC 50111-509-03

Atenolol and Chlorthalidone Tablets, USP

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

1000 Tablets



EACH TABLET CONTAINS:

Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as
defined in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.



SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936

Control No.:
Exp. Date:
Iss. 5/96

NDC 50111-509-03

Atenolol and Chlorthalidone Tablets, USP

100 mg/25 mg

CAUTION: Federal law prohibits
dispensing without prescription.

1000 Tablets



EACH TABLET CONTAINS:

Atenolol, USP 100 mg
Chlorthalidone, USP 25 mg

Dispense in a well-closed container as
defined in the USP.

Store at controlled room temperature
15°-30°C (59°-86°F).

USUAL DOSAGE: One tablet daily, or as
directed by physician. See package insert.



SIDMAK LABORATORIES, INC.
East Hanover, NJ 07936

Control No.:
Exp. Date:
Iss. 5/96